510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number: #K042919

B. Purpose for Submission: New device

C. Measurand: Fibrinogen

D. Type of Test: Quantitative

E. Applicant: R2 Diagnostics

F. Proprietary and Established Names: FibroTek FIB Fibrinogen Assay Kit; Fibrinogen Test

G. Regulatory Information:

1. Regulation section: 21 CFR Section 864.7340 – Fibrinogen Determination System

2. Classification: Class II

3. Product code: GIS, KQJ

4. Panel: Hematology (81)

H. Intended Use:

1. Intended use(s): The FibroTek FIB Fibrinogen Kit is intended for use in the quantitative determination of fibrinogen in citrated human plasma.

2. Indication(s) for use: Same as Intended Use.

3. Special conditions for use statement(s): The Kit should only be used in an appropriate clinical laboratory by qualified laboratory professionals on diluted plasma samples in the general patient population; and for patients having possible fibrinogen disorders.

4. Special instrument requirements: The Kit may be used on automated or semi-automated, mechanical or photo-optical coagulation analyzers.

I. Device Description:

The FibroTek FIB Kit contains (5) x 2 ml lyophilized human thrombin reagent (~ 100 NIH units/mL); (3) x 1 mL calibrator plasma; (1) x 135 mL Imidazole Buffered Saline (IBS), stabilizers and preservatives. It is based upon the Clauss method, and contains enough reagent for (100) determinations of fibrinogen.

J. Substantial Equivalence Information:

1. Predicate device name(s): (Fisher Diagnostics) Pacific Hemostasis Fibrinogen Assay Set

2. Predicate 510(k) number(s): #K800826

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Assay type	Clauss-based thrombin clotting assay	Same
Intended Use	Quantitative fibrinogen determination	Same
Components	Thrombin reagent, calibrator plasma and Imidazole buffered saline	Same
Test methods	Manual; automated or semi-automated, photo-optical and mechanical instruments.	Same
Precision	< 10% CV	
Interference (possible)	Hemoglobin, bilirubin and lipids	Same

Differences		
Item	Device	Predicate
Thrombin reagent source	Human	Bovine
Precision	< 8.0% CV	< 6.0% CV

K. Standard/Guidance Document Referenced (if applicable):

NCCLS Documents -

1. C28-A2 – How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - 2nd Ed.

2. EP7-A – Interference Testing in Clinical Chemistry; Approved Guideline.

3. EP9-A2 – Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - 2nd Ed.

4. H21-A2 – Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline – 2nd Ed.

5. H30-A2 – Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline - 2nd Ed.

L. Test Principle:

This is a one-stage, quantitative test performed on diluted plasma. It is based on the Clauss method, which utilizes thrombin. When excess thrombin is added to dilute plasma, fibrinogen is inversely proportional to clot time in seconds. The test is a manual procedure, but may be run on automated mechanical or photo-optical instrumentation.

M. Performance Characteristics (if/when applicable):

1. Analytical performance: All testing was performed on the Stago STA Compact (mechanical) and MLA 1000C (photo-optical) analyzers.

a. *Precision/Reproducibility:* (3) levels of quality control (QC) plasmas (PlasmaCon N, L-1 and L-2) were tested. The acceptance criterion was precision of < 10% CV.

Within-run precision was determined on (10) vials, each, pooled plasma, tested in duplicate. All %CV's ranged 1.9 – 7.1%.

Between-run precision was done on (2) vials, each, pooled plasma, tested in duplicate, over (5) days. All %CV's ranged 1.72 – 7.34%.

b. *Linearity/assay reportable range:* This was determined from linear regression ranges on respective analyzers. MLA = ~50 – 600 mg/dL; STA = ~100 – 800 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* This is a Clauss-based functional clotting assay, and uses a lyophilized normal human calibrator plasma that has been assayed for fibrinogen value.

d. *Detection limit:* N/A

e. *Analytical specificity:* Comparative interference studies were performed, in duplicate, between the proposed and predicate devices. Two (2) ml plasma samples were tested, and contained varying levels of bilirubin, hemoglobin, lipids, Argatroban and hirudin,. Results were displayed in bar graphs to demonstrate similar mean values for both assays on both analyzers.

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:* Studies were performed on normal and abnormal plasma samples (N = 110), from CliniSys Associates on both analyzers. Sample distribution was (30), each, normal, high and low fibrinogen plasmas; (10) plasmas containing fibrin degradation products; and (5), each high and low heparinized plasmas. Regression statistics for both instruments were:

MLA	**STA**
y = 0.8592x + 8.565; R2 = 0.9693	y = 0.8479x + 21.941; R2 = 0.9582
Range = 50 – 600 mg/dL	Range = 100 – 800 mg/dL

b. *Matrix comparison:* N/A

3. Clinical studies:

a. *Clinical Sensitivity:* N/A

b. *Clinical specificity:* N/A

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:** N/A

5. Expected values/Reference range: Testing was performed to establish reference ranges for both instruments, using normal samples (N = 120). Results were:

	MLA	STA
Sample Range	149 – 465 mg/dL	296 – 413 mg/dL
Mean	320 mg/dL	351 mg/dL
Reference range	263 – 383 mg/dL	296 – 413 mg/dL

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.